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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,072	01/02/2004	Sven Eyckerman	2676-6264US	2266
24247	7590	10/07/2004	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			HOWARD, ZACHARY C	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 10/07/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/751,072	<b>Applicant(s)</b> EYCKERMAN ET AL.	
	<b>Examiner</b> Zachary C Howard	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### DETAILED ACTION

1. Claims 1-21 are pending in the instant application.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, 11, 13, 15, and 16, drawn to a fusion protein comprising a ligand binding domain and a bait domain, classified in class 530, subclass 350.
- II. Claims 9, 10, 12, and 14, drawn to a prey polypeptide, classified in class 530, subclass dependent on species.
- III. Claims 17-21, drawn to a method of screening compounds that disrupt compound-compound binding, classified in class 435, subclass 7.21.

The inventions are distinct, each from the other because of the following reasons:

2. Although there are no provisions under the section "for Relationship of Inventions" in the M.P.E.P § 806.05 for inventive groups that are directed to different products, restriction is deemed proper because these products constitute patentably distinct inventions for the following reasons. Inventions I and II are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Invention I requires search and consideration of a recombinant receptor comprising a ligand binding domain and heterologous bait

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domain, which is not required by Invention II. Invention II requires search and consideration of a prey polypeptide that interacts with a bait polypeptide and comprises an inhibitor of activation of a receptor, which is not required by invention I. While the specification recites a number of species of these inventions that are designed to function together, each of Inventions I and II as claimed is a broadly drawn genus of polypeptides that can be used independently of each other. The recombinant receptors of Invention I can be used with a variety of prey polypeptides other than those of Invention II, such as prey polypeptides comprising an activator of a receptor, or prey polypeptides with innumerable other cellular activities or functions. The genus of prey polypeptides of Invention II includes any possible natural occurring polypeptide that interacts with a bait polypeptide and comprises an inhibitor of activation of a receptor. As claimed, this genus is not limited to interacting with a recombinant receptor of Invention I and could be used with a variety of naturally occurring bait receptors or other bait proteins rather than those of Invention I. Further, as this genus encompasses naturally occurring polypeptides, there are many other independent uses for these polypeptides such as methods of generating antibodies.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case in addition to a method of screening for compounds that disrupt compound-compound binding, the

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recombinant receptor comprising a bait domain could also be used in a method of screening compounds for that bind to the bait domain (i.e., a method of screening for prey polypeptides).

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case in addition to a method of screening for compounds that disrupt compound-compound binding, the prey polypeptide comprising a bait-interacting polypeptide and inhibitor of a receptor could also be used to screen for bait polypeptides, or in a method of generating antibodies (as described above).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

### **Species Election**

3. Claims 7 and 19 of this application are directed to the following patentably distinct species of the claimed invention: modification states of heterologous bait peptide including phosphorylation, acetylation, acylation, methylation, ubiquitination or glycosylation.

If Group I or III is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 6, 8 and 18 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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4. Claims 1-21 are generic to a plurality of disclosed patentably distinct species of recombinant receptor and prey polypeptide pairs. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If Group I or III is elected, Applicant is required to elect one of the following:

a) a specific recombinant receptor comprising both a specific ligand binding domain (the extracellular portion of LR or EpoR) *and* a specific domain that comprises a heterologous bait polypeptide (EpoR, p53, or ALK4).

If Group II or III is elected, Applicant is required to elect one of the following:

b) a specific prey polypeptide comprising both a specific polypeptide that interacts with a bait polypeptide (CIS, SVT, or FKBP12) *and* a specific polypeptide comprising an inhibitor of activation of a receptor and/or a recruitment site for an inhibitor of activation of a receptor (PTP-1b, a specific SHP, a specific protein tyrosine phosphatase, SOC1, SOCS3, a specific suppressor of cytokine signaling, a specific JAK phosphatase, a specific STAT phosphatase, PIAS3, or a specific protein inhibitor of activated STAT).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. A telephone call was made to Allen C. Turner on 9/24/2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in cursive script that reads "Eileen B. O'Hara".

**EILEEN B. O'HARA**  
**PATENT EXAMINER**